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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,919	02/04/2004	Joseph K. Belanoff	019904-002610US	5231

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/772,919

Applicant(s)

BELANOFF, JOSEPH K.

Examiner

Benjamin J. Packard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date (1 sheet).

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-11 in the reply filed on 7/18/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction of Groups I and II is made FINAL.

Upon further consideration, examiner now withdraws the species election because while the individual compounds are distinct, the class of glucocorticoid receptor antagonists are fairly well known and would not be a burden to search.

Claims 1-11 of Group I are now examined.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Specification

The attempt to incorporate subject matter into this application by reference to documents listed in paragraph 46 is ineffective because the foreign applications and non-patent literature are not allowed to be incorporated by reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHATZBERG, et al. (US 6,150,349).

1. A method of ameliorating the symptoms of postpartum psychosis in a patient in need thereof,

While the earlier '349 teaches the treatment (inherently ameliorating) of "major depression" (see claim 1), which includes postpartum psychosis where '349 teaches multiple forms of postpartum psychosis ("postpartum psychosis that does not meet other DSM IV categories" column 15 lines 55-56).
comprising administering an amount of a glucocorticoid receptor antagonist effective to ameliorate the symptoms of the postpartum psychosis,

See claim 1.

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with the proviso that the first psychotic symptoms arise within nine months of childbirth, that the patient has never suffered any psychotic condition not triggered by childbirth, and that the patient did not suffer from psychosis prior to parturition.

Description of the patient population, where the major depression-type postpartum psychosis includes these parameters.

2. The method of claim 1, wherein the first psychotic symptoms arise within eight weeks of childbirth.

The term postpartum inherently means beginning in or extending into the postpartum period, which includes the first eight weeks after childbirth.

3. The method of claim 1, wherein the glucocorticoid receptor antagonist comprises a steroidal skeleton with at least one phenyl-containing moiety in the 11- β position of the steroidal skeleton.

See claim 2 and column 3 lines 56-61.

4. The method of claim 3, wherein the phenyl-containing moiety in the 11- β position of the steroidal skeleton is a dimethylaminophenyl moiety.

See claim 3 and column 3 lines 56-61.

5. The method of claim 4, wherein the glucocorticoid receptor antagonist comprises mifepristone.

See claim 4 and column 5 lines 13-21.

6. The method of claim 4, wherein the glucocorticoid receptor antagonist is selected from the group consisting of 11 β -(4-dimethylaminoethoxyphenyl)-17 α -propynyl-17 β -

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hydroxy-4,9 estradien-3-one and 17 β -hydroxy-17 α -19-(4-methylphenyl)androsta-4,9(11)-dien-3-one.

See column 10, lines 17-20 which teaches RU044, 17 β -hydroxy-17 α -19-(4-methylphenyl)androsta-4,9(11)-dien-3-one, as another GR antagonist.

9. The method of claim 1, wherein the administration is once per day.

See claim 10.

10. The method of claim 1, wherein the mode of administration is oral.

See claim 11.

11. The method of claim 1, wherein the mode of administration is by a transdermal application, by a nebulized suspension, or by an aerosol spray.

See claim 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al. (US 6,150,349) in view of BRADLEY et al, J. Med. Chem. 45, 2417-2424 (2002).

SCHATZBERG, et al does not teach when the specific glucocorticoid receptor antagonists listed in claim 7.

BRADLEY et al, J. Med. Chem. 45, 2417-2424 (2002) teach GR antagonist compounds (see title, abstract, and pg 2417 first full paragraph) 4 α (S)-Benzyl-2(R)-prop-1-ynyl- 1,2,3,4,4 α ,9,10,10 α (R)-octahydro-phenanthrene-2,7-diol diol (pg 2421 3rd full paragraph) and 4 α (S)-Benzyl-2(R)- chloroethynyl-1,2,3,4,4 α ,9,10,10 α (R)-octahydro-phenanthrene-2,7-diol (pg 2421 2nd full paragraph). Therefore, one skilled in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, and would have a reasonable expectation of success.

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Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al. (US 6,150,349) as applied to claim 1 above, and further in view of GEBHARD (US 6,011,025).

SCHATZBERG, et al does not teach when the specific glucocorticoid receptor antagonists listed in claim 8.

GEBHARD claims the glucocorticoid receptor antagonist (11 β ,17 β)-11-(1,3-benzodioxol-5-yl)-17-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one (see abstract and claim 6). Therefore, one skilled in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, , and would have a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 10-12 of SCHATZBERG, et al. (US 6,150,349) (hereafter '349). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed to methods of treating depression. See the above 102 and 103 arguments above for support of the anticipation and obviousness.

Conclusion

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 September 2007
BP


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